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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/063,937 | 05/28/2002 | Brent C. Gerberding | S63.2-10447 | 2387 |

490 7590 04/05/2005

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

HOUSTON, ELIZABETH

| ART UNIT | PAPER NUMBER |
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3731

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------|----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/063,937 | GERBERDING, BRENT C. | |
| | Examiner | Art Unit | |
| | Elizabeth Houston | 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/08/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,13-18,22-28 and 34-36 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7-10,13-18,22-28, and 34-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 May 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the special struts at one or both ends of the stent as in claims 9,10 and 23 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Response to Amendment

2. The withdrawal of the rejection to claims 16 and 17, which are rejected under U.S.C. 102(e) as being anticipated by Cox (USPN 6,652,579), is respectfully denied. Applicant has amended claim 16 to recite in part "at least one annular section of interconnected serpentine segments having a proximal and a distal end, there being a plurality of special struts disposed adjacent to the proximal end of the annular section and a plurality of special struts disposed adjacent to the distal end of the annular section." Applicant states that Cox does not teach or suggest a stent with this combination of features; however, Cox states that the number and location of the special struts can be varied (Col 4, lines 4-14). This implies that there could be more than one special strut located between every other cylindrical ring. Thus, the stent would have at least one annular section of interconnected serpentine segments having a proximal and a distal end, with a plurality of special struts disposed adjacent to the distal and proximal ends of the annular section. As to claim 17, the special struts are in a region between the ends of the stent.

3. The withdrawal of rejection as to claim 25 is respectfully denied. Examiner has pointed out that Cox does teach the new combination of features as stated above, and therefore claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Thronton.

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4. The combination of Wolinsky (USPN 6,730,116) and Erbel (2004/0116998) is proper and so rejection of original claims 4 and 5 under 35 U.S.C. 103(a) is respectfully upheld. Furthermore claims 1, 2, 9, 10, 15, 26, 28, 34 and 35 are rejected under U.S.C. 103(a) as being unpatentable over Wolinsky in view of Erbel. Applicant states that there is no motivation to incorporate the markers of Wolinsky in to the stent of Erbel.

Examiner is not providing motivation to incorporate the special struts of Wolinsky into the stent of Erbel, but rather is incorporating the cover of Erbel and the placement and location of radiopaque markers around the cover into the stent of Wolinsky. . Erbel provides the motivation that using a cover on the stent enhances the properties of the stent as it could then be used to treat aneurysms and tears. Further, using the cover at the location of the radiopaque markers augments the ease of use. Erbel teaches that the non-porous section "will cause thrombosis or clotting of bodily fluid" (Para 83) as in treating an aneurysm. The partial non-porous or graft covering is beneficial in that it blocks the tear or lesion or aneurysm, while at the same time allows blood to flow from the proximal to the distal end of the vasculature during implantation of the device. (Para70-72). Erbel also teaches that the "use of such radiopaque markers facilitates correct placement" of the stent (Para 90). Furthermore, Wolinsky does teach that more markers can be added to the ends of the stents to permit the markers to always be visible regardless of the rotational orientation of the stent (Col 9, lines 5-10). The combination is proper and the rejection is respectfully upheld.

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5. The withdrawal of the rejection of claims 13 and 14 is respectfully denied.

Applicant states that there are different structural limitations present in radiopaque material that is plated, coated, painted, welded or swaged and so the products are different. While examiner agrees that ultimately the properties of the material will change depending on how it is processed, examiner disagrees that each process claims a different product. Ultimately the claim is stating that the material is radiopaque. How it becomes radiopaque or how it is attached to the stent does not change the fact that the end product is radiopaque material. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted). (See MPEP § 2113)

Claim Rejections - 35 USC § 102

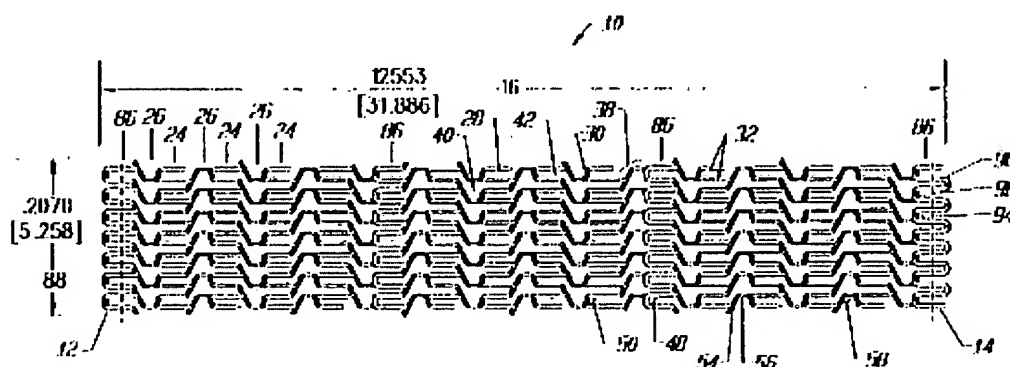
6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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7. Claim 36 is rejected under 35 U.S.C. 102(e) as being anticipated by Jang (USPN 6,241,760).
8. Jang discloses a stent (Fig. 7A) comprising a first end region and a second end region and a central region. The pattern of struts in the central region (only expansion columns 24) differs from the patterns of struts in the first and second regions (expansion columns 24 and reinforcement expansion columns 86) (Col 10, line 2). Jang states that the stent are typically partially plated with radiopaque material by plating both ends from 1 to 3 or more expansion columns. In that respect the ends could be coated up to 6 expansion columns thereby delineating the central region of the stent.



Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-2, 4-5, 7-10, 15-18, 22-27, and 28-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Erbel. In light of the amendments submitted by the applicant, examiner still upholds the arguments as being unpatentable in light of the prior art.

11. Cox discloses the stent in claim 16 and 17 as stated above. As to claim 1, in one embodiment, Cox clearly teaches a stent having a longitudinal axis, comprising a plurality of interconnected struts (Figs. 6) with special struts (54) having enlarged width (Col. 7, line 16), having a first side with a first region of first curvature relative to the longitudinal axis and a second side with a second region of second curvature relative to the longitudinal axis, the first region opposite the second region and having a radiopaque marker (Col. 3, line 14) between the two regions. As to claims 2 and 17, there are pluralities of special struts, which are located between the ends of the stent. As to claims 8 and 22, some of the special struts (54b or 54c) are located anywhere between the middle of the stent and halfway from the middle to the end of the stent. As to claims 16, 24 and 28, the region with the enlarged width is substantially circular or bulbous and has a greater radiopacity than the rest of the strut. In other embodiments disclosed by Cox (Figs. 11-15), there is a plurality of radiopaque markers and special struts at the end of the stent as claimed in claims 9, 10, and 23. As to claim 27, Cox states that the number and location of the special struts can be varied (Col 4, lines 4-14), implying that the stent could have special struts in locations other than the end of the stent.

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12. Cox does not disclose a stent with a cover.

13. As to claims 1, 18, and 26, Erbel discloses an endovascular prosthesis (Fig. 3) or stent (20) comprising at least one cover (25) disposed about at least one section of interconnected serpentine segments, marked at the distal end and proximal end by a plurality of radiopaque markers (35). Erbel teaches that the "use of such radiopaque markers facilitates correct placement" of the stent (Para 90).

14. As to claims 4, 5, 34 and 35, the nonporous section (25) or cover is disposed about the circumference of the stent, but does not extend about an entire circumference of the stent and does not cover the entirety of the stent as seen in Fig. 3. As to claim 7, the cover extends about the medical device in the region of the special struts.

15. Erbel teaches that the non-porous section "will cause thrombosis or clotting of bodily fluid" (Para 83) as in treating an aneurysm. Erbel further teaches that the partial non-porous or graft covering is beneficial in that it blocks the tear or lesion or aneurysm, while at the same time allows blood to flow from the proximal to the distal end of the vasculature during implantation of the device. (Para 70-72).

16. The inventions are analogous with each other and with the instant invention therefore a combination is proper. It would have been obvious to one of ordinary skill in the art to incorporate a cover disposed about the stent in the area of radiopaque markers, which extends circumferentially about the stent but does not cover the entirety of the stent. Erbel provides the motivation that using a cover on the stent enhances the properties of the stent as it could then be used to treat aneurysms and tears. Further using the cover at the location of the radiopaque markers augments the ease of use.

17. Claims 1 and 4-6 rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Erbel as applied to claim 1 above, and further in view of Barone (USPN 6,613,078).

18. Cox in view of Erbel teaches a stent with a cover marked at the periphery by special radiopaque struts. Cox in view of Erbel does not teach a second cover.

19. Barone teaches a stent with two covers shown in Fig. 7. The figure shows two stent grafts occluding where the vessel is ruptured but keeping the flow of the blood through the ostium of the vessel branch. Barone states that the use of 2 covers is desirable to repair blood vessels with lesions wherein the wall of the vessel is not in condition to receive and firmly retain an implanted graft (Col 2, lines 20-25 and Col 1, lines 8-17).

20. At the time of the invention it would have been obvious to one of ordinary skill in the art to combine the second cover of Barone into the stent of Cox in view of Erbel. Barone provides the motivation in that a stent with two covers is enhances the function of the stent since it can be used to repair branched vessels with multiple lesions. The inventions are analogous with each other and the instant invention and so the combination is proper.

Conclusion

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-Th 8:30-6:00 Alternate Fridays 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

3/31/05.